WELSH STATUTORY INSTRUMENTS

2011 No. 2907 (W.311)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011

Made - - - -	*4 December 2011*
Laid before the National Assembly for Wales - -	*6 December 2011*
Coming into force - -	*31 December 2011*

The Welsh Ministers, in exercise of the powers conferred by sections 80, 83 and 203(9) and (10) of the National Health Service (Wales) Act 2006(**1**) hereby make the following Regulations:

Title, commencement, application and interpretation

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011.

(2) These Regulations come into force on 31 December 2011.

(3) These Regulations apply in relation to Wales.

(4) In these Regulations "the principal Regulations" ("*y prif Reoliadau*") means the National Health Service (Pharmaceutical Services) Regulations 1992(**2**).

Amendment of paragraph 25 of Schedule 2 to the principal Regulations

2.—(1) Paragraph 25 (clinical governance) of Schedule 2 to the principal Regulations(**3**) is amended in accordance with the following provisions of this regulation.

(2) After sub-paragraph (1) insert the following sub-paragraph—

"(1A) A system of clinical governance is "acceptable" if it provides for—

(a) compliance with the clinical governance components set out in sub-paragraph (2), and

(**1**) 2006 c. 42.
(**2**) S.I. 1992/662. Relevant amending instruments are S.I. 2005/1013 (W.67), S.I. 2007/205 (W.19), S.I. 2009/1491 (W.144), S.I. 2010/868 (W.90) and S.I. 2010/1648 (W.156).
(**3**) Paragraph 25 was inserted into S.I. 1992/662 by S.I. 2005/1013 (W.67) and has been amended by S.I. 2010/868 (W.90).

(b) submission of an annual self assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.".

(3) In sub-paragraph (2), for the words "For these purposes" to "the following components-" substitute the following—

"The clinical governance components comprise of the following—".

(4) In paragraph (a) of sub-paragraph (2)—

(a) after sub-paragraph (ii) insert the following sub-paragraph—

"(iia) a requirement that where the chemist publicises the NHS services that are available at or from the chemist's pharmacy (whether the chemist is producing their own publicity material or advertising services in material published by another person), the chemist does so in a manner which makes clear that the services are funded as part of the health service,"; and

(b) at the end of sub-paragraph (iii) after the comma insert the following—

"including a requirement to publicise the results of the survey and any appropriate action the chemist intends to take,".

(5) In paragraph (c) of sub-paragraph (2)—

(a) at the end of sub-paragraph (iii) after the comma insert the following—

"which comprises of—

(aa) a patient safety incident log,

(bb) a near-miss log, and

(cc) the reporting of patient safety incidents to the National Patient Safety Agency,";

(b) after sub-paragraph (iii) insert the following sub-paragraph—

"(iiia) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare products Regulatory Agency and the National Patient Safety Agency,"; and

(c) for sub-paragraph (vi) substitute the following sub-paragraph—

"(vi) a clinical governance lead person for each pharmacy, appointed as such by the chemist (or that is the chemist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,".

(6) In paragraph (e) of sub-paragraph (2)—

(a) omit the "and" at the end of sub-paragraph (iv);

(b) for the semicolon at the end of sub-paragraph (v) substitute ", and"; and

(c) after sub-paragraph (v) insert the following sub-paragraph—

"(vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the chemist—

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**4**) (meaning of

(**4**) 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of "worker" for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the National Health Service (Wales) Act 2006.